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EXAMINER	
GREENE, IVAN A	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/564,635	FUNDA ET AL.
	Examiner	Art Unit
	IVAN GREENE	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-5 and 7-21 are currently pending and are currently being examined on the merits. Applicant has canceled claim 6 and incorporated that subject matter into independent claims 1 and 15.

Advisory Notice

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New grounds of rejection necessitated by amendment: Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Claim 15 recites the new matter "wherein the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% and wherein the milk protein composition additionally contains a plant protein, whereby either the milk protein is hydrolyzed or the plant protein is a plant protein hydrolysate or whereby the milk protein is partially hydrolyzed and the plant protein is a plant protein hydrolysate."

Applicant has amended claim 15 to include the subject matter of claim 6 which did not originally depend from claim 15 but rather claim 1. Instant claim 15 is distinguished over claim 1 by the claim language "the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%".

The originally filed disclosure does not include language indicating the species hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% in combination with either a plant protein or a plant protein hydrolysate, as currently recited in claim 15. The instant specification as filed included in Example 2 the disclosure of a powderous formulation which includes the protein that is sodium caseinate (a milk protein) having a degree of hydrolysis of about 3.5%, and does not include a plant protein or a plant protein hydrolysate. Additionally, as per applicant's arguments and § 1.132 declaration originally disclose Example 2 is now considered a comparative example distinguished from the instantly claimed invention in that it does not include a plant protein or plant protein hydrolysate.

A person having ordinary skill in the art, in view of applicants originally filed disclosure, would not have clearly recognized the contemplation of a powderous formulation comprising a milk protein composition wherein the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% and wherein the milk protein composition additionally contains a plant protein, whereby either the milk protein is hydrolyzed or the plant protein is a plant protein hydrolysate or whereby the milk protein is partially hydrolyzed and the plant protein is a plant protein hydrolysate.

Claim Rejections - 35 U.S.C. 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

New grounds of rejection necessitated by amendment: Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites "wherein the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% and wherein the milk protein composition additionally contains a plant protein, whereby *either the milk protein is hydrolyzed or the plant protein is a plant protein hydrolysate* or whereby the milk protein is partially hydrolyzed and the plant protein is a plant protein hydrolysate." The emphasized claim language above indicates that the milk protein is hydrolyzed **or** the plant protein is a plant protein hydrolysate, which covers the embodiment wherein the milk protein is not a hydrolysate but rather the plant protein is a plant protein hydrolysate. However, the claim also recites that "the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%," rendering the claim indefinite because it is not clear whether the milk protein is required to be a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%. Appropriate clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

New grounds of rejection necessitated by amendment: Claims 1-5, 7-14, 16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636; published October, 1994) in view of SCHMIDT (US 4,395,422; published July, 1983), CHO (US 4,025,659; published May, 1977) and KODERA (US 6,455,273; published September, 2002).

SCHNEIDER teaches a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film- forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment (abstract). SCHNIDER further teaches that their vitamin powder compositions are suitable for use in premixes, pellets and extrudates for animal feed, and tablets for the drug sector (col. 2, lines 27-29).

SCHNEIDER further teaches the fat-soluble vitamins include vitamins A, E, D and K as well as mixtures thereof can be employed in the form of *vitamin solutions in oils* such as products contain vitamin A and its derivatives, especially vitamin A acetate, vitamin A palmitate (3:59-66). SCHNEIDER further teaches the sugars can be any reducing sugars or syrup

containing reducing sugars including fructose, glucose, lactose, maltose, xylose, arabinose, ribose and invert sugar (4:11-17). SCHNEIDER further teaches that it is advantageous to add to the dispersion other compounds customary in the preparation of active substance dry powders (4:59-63). SCHNEIDER goes on to teach the additives starch, maltodextrin, alginates (5:8-9) and hydrophobic silica (4:42).

The difference between the rejected claims and the teachings of SCHNEIDER is that SCHNEIDER does not expressly teach the recited milk protein composition containing a plant protein and a milk protein such as casein; or a plant protein hydrolysate with an average molecular weight of less than 2500 Daltons. These deficiencies in milk protein composition containing a plant protein and a milk protein such as casein; and a plant protein hydrolysate with an average molecular weight of less than 2500 Daltons are cured by the combined teachings of SCHMIDT, CHO and KODERA.

SCHMIDT teaches spray dried vitamin E powders comprising 1 to 25 percent by weight hydrolyzed gelatin and 20 to 30 percent by weight caseinate (abstract.) SCHMIDT further teaches the caseinate is preferably sodium caseinate (col. 2, lines 16-21).

CHO teaches their invention generally relates to composition of soy protein isolates and caseinate which exhibit desirable functional properties; and to a coffee whitener composition comprising a milk protein composition which is a combination of soy protein isolate and caseinate having a relative soy:caseinate weight ratio of about 10:90 to about 80:20 (col. 1, lines 1-15; & col. 2, lines 11-16). CHO further teaches the preferable caseinate is the species sodium caseinate (col. 2, lines 67-68). CHO further teaches a reducing sugar species corn syrup solids

having a dextrose equivalent of 24 (col. 6, line 2). CHO further teaches the oil species corn oil (col. 4, line 37).

KODERA teaches that enzymatic protein hydrolysates have excellent functional properties but suffer from strong bitterness (col. 1, lines 43-45). KODERA further teaches that their invention utilizes a protease enzyme to reduce the bitterness of the protein hydrolysate product (col. 2, lines 44-67). KODERA further teaches the protein substrate examples including casein, soybean protein and mixtures of different proteins (col. 4, lines 9-19). KODERA further teaches the range of the molecular weights of the protein hydrolysate is preferably 200 to 2000 Daltons (4:28-32). KODERA further teaches the product of their invention can be used by incorporation into a variety of food products (4:56-63).

Regarding the claimed dextrose equivalents of the starch hydrolysates, where the claimed prior art products are substantially identical in structure or composition or are produced by identical or substantially identical processes a *prima facie* case of either anticipation or obviousness has been established. Absent evidence to the contrary the prior art composition must possess the claimed dextrose equivalents since it is substantially identical to the claimed composition (See MPEP 2112.01).

A *prima face* case of obviousness based upon a combination rationale requires (1) a finding of fact that the prior art included each element clamed, although not in a single prior art reference, with the only difference between the clamed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding of fact that one of ordinary skill in the art could have combined the elements as claimed by known methods, and

that in the combination, each element merely performs the same function as it does separately; (3) a finding that the one of ordinary skill in the art would have recognized that the results of the combination were predictable; and (4) whatever additional findings based upon the *Graham* factual inquiries may be necessary, in view of the case under consideration, to explain a conclusion of obviousness (MPEP § 2143-A). In the instant case each element of the claimed invention is taught: SCHNEIDER stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film- forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment; SCHMIDT teaches similar spray dried vitamin E powders comprising hydrolyzed gelatin and sodium caseinate; CHO teaches a functional milk protein composition which is a combination of soy protein isolate and caseinate (having a relative soy:caseinate weight ratio of about 10:90); and KODERA teaches an improve protein hydrolysate such a soy protein hydrolysate having excellent functional properties and low bitterness, accordingly item (1) above is satisfied. In the instant case a person having ordinary skill in the art could have utilized a combination of hydrolyzed soy protein and (hydrolyzed) sodium caseinate as the protein component in the invention of SCHNEIDER. Furthermore, a person having ordinary skill in the art would have clearly recognized that the combination of hydrolyzed soy protein and (hydrolyzed) sodium caseinate protein component would have functioned as a protein component composition functions when utilized as a protein component in the wall structure of a protein microcapsule. Accordingly, item (2) above is satisfied. A person having ordinary skill in the art would have recognized that the combination of soy protein isolate and caseinate, having

been taught as a functional food protein, would have predictably functioned as a functional food protein. Accordingly, item (3) above is satisfied. Regarding item (4) additional findings of fact, it is clear that items (1) through (3) are sufficient to support the instant *prima facie* case of obviousness, however, the additional motivation to substitute a portion of the casein protein for soy protein hydrolysate exists in that the casein is a more expensive product (see, e.g., US 5,360,073: col. 1, lines 23-25). Additionally, the skilled artisan would have been motivated to use casein in the invention of SCHNEIDER because the milk protein would have provided improved nutritional value for mammals[1].

New grounds of rejection necessitated by amendment: Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636; published October, 1994) in view of SCHMIDT (US 4,395,422; published July, 1983), CHO (US 4,025,659; published May, 1977) and KODERA (US 6,455,273; published September, 2002) as applied to claims 1-5, 7-14, 16 and 18-21 above, and further in view of BUIKSTRA (US 5,650,190; published July, 1997) and/or MARTINEZ (US 5,589,357; published December, 1996).

SCHNEIDER teaches stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a (gelatin) protein composition (abstract; claim 1, cols. 1 & 2).

The difference between the rejected claim and the teachings of SCHNEIDER is that SCHNEIDER does not expressly teach the partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%. This deficiency in the hydrolyzed milk protein is cured by

[1] See, for example, Brody, Tom; "Nutritional Biochemistry", 2nd ed. 1999, p. 469 § "Protein Quality" first paragraph; Friedman, Mendel; J. Agric Food Chem., Vol. 44, pp. 6-29, particularly p. 8, col. 1, last paragraph; and Hui, Y. H., Editor; Somogyi, Laszlo, P., author; "Handbook of Food Science, Technology, and Engineering," 2006; TAYLOR & FRANCIS; Ch. 83 "Food Additives," p. 83-20, paragraph bridging columns 1 & 2.

BUIKSTRA and/or MARTINEZ.

BUIKSTRA teaches heat-stable oil-in-water emulsions stabilized by hydrolysate comprising hydrolyzed protein wherein the protein is a hydrolysate of *casein having a degree of hydrolysis of 15% to 70%* (title, abstract, 3:12-34).

MARTINEZ teaches a milk protein partial hydrolysate comprising a mixture of whey protein and *casein wherein the degree of hydrolysis is between 4 and 10%* which is prepared by enzymatic hydrolysis, and is suitable for infant formula because it has a reduced antigenicity (abstract). MARTINEZ further teaches that a common characteristic of protein hydrolysates, particularly casein hydrolysates, is a bitter flavor development due to the liberation of peptides with hydrophobic end groups (col. 1, lines 54-57).

The instantly claimed range of partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% would have been *prima facie* obvious in view of BUIKSTRA and/or MARTINEZ because the degree of hydrolysis range taught by the references overlaps with the instantly claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (see MPEP §2144.05-I). Furthermore, as per MPEP § 2144.05-II (A), "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)".

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at

the time the claimed invention was made to utilize the hydrolyzed casein protein, as taught by BUIKSTRA and/or MARTINEZ, in the stable powderous formulations of SCHNEIDER because both BUIKSTRA and MARTINEZ teach hydrolyzed casein proteins suitable for stable dry powdered food additives containing a fat-soluble vitamin ingredients.

New grounds of rejection necessitated by amendment: Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636; published October, 1994) in view of SCHMIDT (US 4,395,422; published July, 1983), CHO (US 4,025,659; published May, 1977) and KODERA (US 6,455,273; published September, 2002).

Regarding claim 17, drawn to a process for the preparation of formulations according to claim 1, SCHNEIDER teaches a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising (1) preparing an aqueous emulsion of the fat-soluble active ingredient, a film- forming colloid (gelatin) and a reducing sugar; (2) converting the emulsion into a dry powder; and (3) submitting the dry powder to cross-linking of the proteins by heat treatment, as discussed above (abstract).

The difference between the rejected claims and the teachings of SCHNEIDER is that SCHNEIDER does not expressly teach the recited milk protein composition containing a plant protein hydrolysate and a milk protein such as casein. These deficiencies in milk protein composition containing a plant protein hydrolysate and a milk protein such as casein are cured by the combined teachings of SCHMIDT, CHO and KODERA, as discussed above.

A *prima face* case of obviousness based upon a combination rationale requires (1) a finding of fact that the prior art included each element clamed, although not in a single prior art

reference, with the only difference between the clamed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding of fact that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in the combination, each element merely performs the same function as it does separately; (3) a finding that the one of ordinary skill in the art would have recognized that the results of the combination were predictable; and (4) whatever additional findings based upon the *Graham* factual inquiries may be necessary, in view of the case under consideration, to explain a conclusion of obviousness (MPEP § 2143-A). In the instant case each element of the claimed invention is taught: SCHNEIDER stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film-forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment; SCHMIDT teaches similar spray dried vitamin E powders comprising hydrolyzed gelatin and sodium caseinate; CHO teaches a milk protein composition which is a combination of soy protein isolate and caseinate (having a relative soy:caseinate weight ratio of about 10:90); and KODERA teaches an improve protein hydrolysate such a soy protein hydrolysate having excellent functional properties and low bitterness, accordingly item (1) above is satisfied. In the instant case a person having ordinary skill in the art could have utilized a combination of hydrolyzed soy protein and (hydrolyzed) sodium caseinate as the protein component in the invention of SCHNEIDER. Furthermore, a person having ordinary skill in the art would have clearly recognized that the combination of hydrolyzed soy protein and (hydrolyzed) sodium caseinate protein component would have functioned as a protein component composition

functions when utilized as a protein component in the wall structure of a protein microcapsule. Accordingly, item (2) above is satisfied. A person having ordinary skill in the art would have recognized that the combination of soy protein isolate and caseinate, having been taught as a functional food protein, would have predictably functioned as a functional food protein. Accordingly, item (3) above is satisfied. Regarding item (4) additional findings of fact, it is clear that items (1) through (3) are sufficient to support the instant *prima facie* case of obviousness, however, the additional motivation to substitute a portion of the casein protein for soy protein hydrolysate exists in that the casein is a more expensive product (see, e.g., US 5,360,073: col. 1, lines 23-25).

Response to Arguments:

Applicant's arguments filed 04/07/2011 have been fully considered but they are not persuasive.

Applicant's argument's rely on the 37 CFR § 1.132 declaration filed 04/07/2011 in which applicant argues the data show an increased retention of Vitamin A content after a cross-linking heat treatment (125°C for 25 minutes) with the samples that include soy protein hydrolysate or rice protein hydrolysate.

Response to Applicant's 37 CFR 1.123 declaration:

Applicant's arguments filed 04/07/2011 have been fully considered but they are not sufficiently persuasive to overcome the rejection based upon obviousness.

The presented data shows a comparison of four formulations including the three examples in the originally filed disclosure and one additional example. The amended claims differ from the originally disclosed examples 1 and 2 in that they require a plant protein hydrolysate component, accordingly, originally disclosed examples 1 and 2 are now considered comparative examples (arguments, p. 5, lines 9-10). The inventive example 3 includes sodium caseinate and a soy protein hydrolysate in a ratio of about 9:1 (i.e. 72.4 g sodium Casein and 8 g soy protein hydrolysate); and the instantly presented example includes a sodium caseinate and rice protein hydrolysate in a ratio of about 4:1 (i.e. 72 g sodium caseinate and 18 g rice protein hydrolysate). The presented data shows a loss of vitamin A content of approximately 30-40 % for the comparative examples and a loss of vitamin A content of approximately 10-20 % for the inventive examples.

The presented data is not considered sufficient to overcome the instant *prima facie* case of obviousness for the following three reasons: (1) it is not considered a true side-by-side experimental showing because the experiments were not conducted at the same time under the same laboratory conditions; (2) the showing in not considered commensurate in scope with the instantly claimed invention because the claims are drawn to any "fat-soluble active ingredient" (a broad genus that cannot be embraced by vitamin A acetate alone), any plant protein hydrolysate, any milk protein including milk protein hydrolysates, and any reducing sugar; and (3) the results are considered a difference in degree rather than a difference in kind because the results show a range of vitamin A loss.

Nonstatutory Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

New grounds of rejection necessitated by amendment: Claims 1-5 and 7-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-9, 11, 13-15, 17, 18 and 20-23 of copending Application No. 10/551,197 (hereafter '197) in view of KODERA (US 6,455,273; published September, 2002) and DOXASTAKIS (Novel Macromolecules in Food Systems, pgs. 7-38).

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein composition, wherein milk protein composition additionally contains a plant protein, whereby either the milk protein is partially hydrolyzed or the plant protein is a plant protein hydrolysate or whereby the milk protein is partially hydrolyzed and the plant protein is a plant protein hydrolysate, and wherein the protein is thermally cross-linked with a reducing-sugar or a reducing sugar derivative selected from a desoxy sugar or an amino sugar wherein the cross-linking of the protein is achieved by

submitting the dry powder to heat treatment. Instant claim 8 claims formulations which further comprise plant protein which is obtained from [...] *lupin protein*. Instant claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; Instant claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claim 14 further limits the reducing sugar to glucose, fructose, saccharose or xylose. Instant claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. Instant claim 21 further limits the plant oil to sunflower oil, palm oil, or corn oil. And instant claim 16 claims a food, beverage, animal feeds, cosmetics or drugs comprising said formulations.

Copending '197 claim 1 recites, a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the group consisting of vitamin A, D, E or K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing. Copending '197 claim 11 recites, a process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein a reducing sugar is added and the composition is submitted cross-linking by heating. Instant claim 7 recites the formulation [...] comprising additionally a plant or animal oil or fat. Copending '197 claim 8 recites formulation [...]

comprising additionally a reducing sugar. Copending '197 claim 15 limits the reducing sugar to glucose, fructose or xylose. Copending '197 claim 13 is similar to Copending '197 claim 11 except the limitation "cross-linking by heating" is replaced with "converting the emulsion to a dry powder." Copending '197 claim 18 recites a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked with a reducing sugar. Copending '197 claims 20-22 recite limitations similar to claims 1 (the active ingredients), claim 7 and claim 15, respectively.

The difference between Copending '197 and the instant claimed invention is that copending '197 does not explicitly teach the use of a milk protein composition comprising a plant protein.

KODERA teaches that enzymatic protein hydrolysates have excellent functional properties but suffer from strong bitterness (col. 1, lines 43-45). KODERA further teaches that their invention utilizes a protease enzyme to reduce the bitterness of the protein hydrolysate product (col. 2, lines 44-67). KODERA further teaches the protein substrate examples including casein, soybean protein and mixtures of different proteins (col. 4, lines 9-19).

DOXASTAKIS teaches lupins belong to the legume group of plants and are able to grow in marginal soils, enabling the plant to grow in many environments (pg. 7, lines 1-6). DOXASTAKIS further teaches, "Interest in a wider utilization of lupin seeds is mainly due to its similarity to soybeans as a high source of protein and to the fact that it can be grown in more temperate climates and is tolerant of poor soils (pg. 7, lines 18-20). .

It would have been *prima facie* obvious to combine copending '197 with the teachings of KODERA/DOXASTAKIS and produce the instant claimed invention because KODERA teaches a method of decreasing the bitterness of a protein hydrolysate such as soybean protein and DOXASTAXIS teaches a suitable protein substrate lupin protein having properties similar to soybean protein but can be grown in poor soils as compared to soybeans. Examiner notes the comprising language of copending '197 invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments:

Applicant's arguments filed 04/07/2011 have been fully considered but they are not persuasive.

The examiner acknowledges applicant's wish to hold the foregoing provisional obvious-type double patenting rejection in abeyance until allowable subject matter is indicated. Applicant is advised that the Patent Office does not hold rejections in abeyance, therefore the rejection is maintained. See MPEP 714.02 and 37 CFR 1.111(b).

Applicant is reminded that the merits of a provisional obviousness-type double patenting rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966).

Conclusion

The prior art made of record and not presently relied upon is considered pertinent to applicant's disclosure. The following foreign patent documents are made of record: an English Language translation of the previously cited German Patent document EP 0982038. The following US patent documents are cited for applicant's consideration: US 2,952,543 teaches the combination of casein and soy protein (see col. 1); US 6,048,562 teaches that various proteins have been used as the wall materials for the encapsulation of various ingredients (col. 1, lines 25-30); and US 2002/0132288 teaches the art recognized property of casein and whey proteins to form bitter tasting hydrolysates (see [0004]).

Claims 1-5 and 7-21 are pending and have been presented for examination on the merits. Claim 15 is rejected under 35 U.S.C. 112, first paragraph; claim 15 is rejected under 35 U.S.C. 112, second paragraph; claims 1-5 and 7-21 are rejected under 35 USC § 103(a); and claims are provisionally rejected on the grounds of nonstatutory obvious-type double patenting over copending 10/551,197. No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Friday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on (571) 272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647